

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/695,048	NELSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kahsay Habte, Ph. D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--  
 being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included  
 or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS  
 OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative  
 ce or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

s communication is responsive to \_\_\_\_\_.

e allowed claim(s) is/are 1-4 and 6-7.

e drawings filed on \_\_\_\_\_ are accepted by the Examiner.

nowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

☐ All ☐ b) ☐ Some\* ☐ c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the  
 International Bureau (PCT Rule 17.2(a)).

ertified copies not received: \_\_\_\_\_.

nt has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements  
 elow. Failure to timely comply will result in ABANDONMENT of this application.

**THREE-MONTH PERIOD IS NOT EXTENDABLE.**

SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF  
 FORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

RECTED DRAWINGS ( as "replacement sheets") must be submitted.

] including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

] including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
 Paper No./Mail Date \_\_\_\_\_.

tying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of  
 sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

POSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the  
 atched Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

ent(s)

ice of References Cited (PTO-892)

ice of Draftsperson's Patent Drawing Review (PTO-948)

rmation Disclosure Statements (PTO-1449 or PTO/SB/08),

per No./Mail Date \_\_\_\_\_

aminer's Comment Regarding Requirement for Deposit

ological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☐ Interview Summary (PTO-413),  
 Paper No./Mail Date \_\_\_\_\_.

7. ☐ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-4 and 6-7, drawn to a process of making bicyclic lactone compounds, classified in class 544, subclass 105.
  - II. Claim 5, drawn to monocyclic intermediate compounds (azetidines, pyrrolidines, piperidines, azepines and azocanes), classified in class 540, 546, 548, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a starting material for preparing compounds that are angiotensin converting enzyme inhibitors and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Note that further restriction of the intermediates (Group II) may be required, if applicants file a divisional application.

During a telephone conversation with Mr. Richard Parr on Dec. 21, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-4 and 6-7. Affirmation of this election must be made by applicant in replying to this Office action. Claim 5 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Richard Parr on Dec. 21, 2004. Enter the following:

1. In claim 1 (page 16, line 5) replace a typographical error "Forumla" with -- Formula--.

2. Delete claim 5.

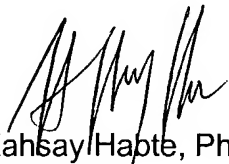
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***Conclusion***

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply within 24 hours, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kahsay Habte, Ph. D.  
Examiner  
Art Unit 1624

  
Mark L. Berch  
Primary Examiner  
Art Unit 1624

KH  
December 22, 2004